

JUN 13 2000

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-152

REVOLUTION™
(selamectin)

"...kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations in cats and dogs. Revolution also is indicated for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*) and for the control of tick (*Dermacentor variabilis*) infestations in dogs, and the treatment and control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. Revolution is recommended for use in dogs and cats six weeks of age and older."

Sponsored by:

PFIZER, INC

NADA- 141-152

FOIS 1

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FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

NADA Number: 141-152

Sponsor: Pfizer Inc.
235 East 42nd St.
New York, NY 10017

Generic Name: Selamectin

Trade Name: Revolution™

Marketing Status: Rx: U.S. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effect of Supplement: Provide additional indication for control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. The indication for the treatment of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats was previously approved with the original approval of Revolution.

II. INDICATIONS FOR USE

Revolution kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations in dogs and cats. Revolution also is indicated for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*) and for the control of tick (*Dermacentor variabilis*) infestations in dogs, and the treatment and control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. Revolution is recommended for use in dogs and cats six weeks of age and older.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND DOSAGE

The recommended minimum dose is 2.7 mg selamectin per pound (6 mg/kg) of body weight. Administer the entire contents of a single dose tube of Revolution topically in accordance with the following tables.

Cats (lb)	Package color	mg per tube	Potency (mg/mL)	Administered volume (mL)
up to 5	Mauve	15 mg	60	0.25
5.1-15	Blue	45 mg	60	0.75

For cats over 15 lbs., use the appropriate combination of tubes

Dogs (lb)	Package color	mg per tube	Potency (mg/mL)	Administered volume (mL)
up to 5	Mauve	15 mg	60	0.25
5.1-10	Purple	30 mg	120	0.25
10.1-20	Brown	60 mg	120	0.5
20.1-40	Red	120 mg	120	1.0
40.1-85	Teal	240 mg	120	2.0

For dogs over 85 lbs., use the appropriate combination of tubes

IV. EFFECTIVENESS STUDIES

Effectiveness and Safety of Selamectin in the Treatment and Control of Natural Infestations of Hookworms and Ascarids in Cats Presented as Veterinary Patients. Study #'s 1283C-60-95-156, 1283C-60-95-158, 1283C-60-95-159, 1283C-60-96-194, and 1283C-60-96-195.

Purpose: To demonstrate the effectiveness and safety of selamectin in the treatment and control of natural infections of nematodes in cats presented as veterinary patients.

Study Locations and Investigators:

Louis Burch, DVM
The Animal Medical Center
340 North 6th Street
Redland, CA 92374
1283C-60-95-158

H. Lee Butler, DVM
280 Veteran's Drive North
Huntington, TN 38344
1283C-60-96-195

Raymond L. Ewing DVM
Atglen Veterinary Hospital
150 Pine Creek Drive
Christiana, PA 17509
1283C-60-95-159

Suzanne M. Hirsch, DVM
Range Avenue Veterinary Hospital
513 North Range Avenue
Denham Springs, LA 70726
1283C-60-96-194

B. Britton Stringer, DVM
River Oaks Animal Hospital
14471 Old Hammond Highway
Baton Rouge, LA 70816
1283C-60-95-156

Animals: Eighty-three cats (36 females and 47 males), 7 weeks to 11 years of age were enrolled. Of these, 70 were considered evaluable for safety and effectiveness. Fifty-one were treated with the test article, selamectin (20 females and 31 males) and 19 (9 females and 10 males) with the control, pyrantel pamoate plus praziquantel. Of the 70 cases evaluated, 7 cats had hookworm infections only, 45 cats had roundworm infections only and 18 cats had both hookworm and roundworm infections.

Dosage Groups: T1: selamectin ≥ 6 mg/kg
T2: pyrantel pamoate (20 mg/kg) plus praziquantel (5 mg/kg) Drontal™

Route of Administration: T1: Topical
T2: Oral tablet

Frequency of Administration: Monthly for 2 months

Duration of Study: 60 days

Parameters measured: Effectiveness was assessed on the basis of a reduction in the number of hookworm and/or roundworm eggs in fecal samples collected from each cat on days 30 and 60, as compared to eggs in fecal samples collected prior to treatment on day 0.

Results: Effectiveness of 6 mg/kg selamectin against *A. tubaeforme* and *T. cati* in cats is shown in the table 1:

Table 1: Geometric Mean Fecal Egg Counts for both Roundworm and Hookworm Infections Prior to Treatment and 30 Days After Each Treatment with % Effectiveness in parenthesis

Treatment ^a	Geometric Mean Roundworm/Hookworm Egg Counts and % Effectiveness ^d		
	Day 0	Day 30	Day 60
Selamectin			
Roundworms ^b	101.3	0.5 ^e (99.5%)	0.0 ^f (100%)
Hookworms ^c	70.9	0.8 ^e (98.8%)	0.0 ^f (100%)
Drontal			
Roundworms ^b	89.6	0.5 ^e (99.4%)	0 ^f (100%)
Hookworms ^c	57.4	1.1 ^e (98.0%)	0.3 ^f (99.5%)

^a Treatments were administered on days 0 and 30

^b There were 49 selamectin-treated cats and 14 Drontal-treated cats.

^c There were 17 selamectin-treated cats and 8 Drontal-treated cats.

^d Day 30 as compared to day 0, day 60 as compared to day 0

^e Day 30 was significantly different from day 0 ($P=0.0001$)

^f Day 60 was significantly different from day 0 ($P=0.0001$)

The 95% confidence intervals for the differences in fecal egg counts between treatment groups on each day are presented in Table 2 and 3 for each species.

Table 2: 95% Confidence Intervals for Hookworms

Day	95%	95%
	Lower Limit	Upper Limit
0	-0.57	2.50
30	-0.70	1.43
60	-0.74	1.07

Table 3: 95% Confidence Intervals for Roundworms

Day	95%	95%
	Lower Limit	Upper Limit
0	-0.58	2.06
30	-0.53	1.05
60	-0.09	0.18

The confidence intervals for the treatment differences indicate that cats in each treatment group had similar fecal egg counts on Day 0 and differed by fewer than 2 eggs per gram of feces on Day 30 onwards.

Conclusions: Selamectin administered topically at monthly intervals at a minimum dose of 6 mg/kg was safe and effective in the control of natural infections of *T. cati* and *A. tubaeforme*.

Adverse Drug Reactions: Two cats treated with selamectin were observed to be drowsy or lethargic following administration of the drug.

V. Animal Safety Studies

Target animal safety studies in support of this supplement are referenced in the FOI Summary for the original NADA 141-152 approval dated May 26, 1999. Additional safety studies were not necessary for this supplemental application.

VI. Human Safety

Data on human food safety, pertaining to consumption of drug residues in food were not required for approval of this supplemental NADA. This drug is labeled for use in dogs and cats which are non-food producing animals.

Human warnings are provided on the product label as follows: "May be irritating to skin and eyes. Wash hands after use and wash off any product in contact with the skin immediately with soap and water. If contact with eyes occurs, then flush eyes copiously with water. In case of ingestion by a human, contact a physician immediately. The material safety data sheet (MSDS) provides more detailed occupational safety information. For a copy of the MSDS or to report adverse reactions attributable to exposure to this product, call 1-800-366-5288

Flammable – Keep away from heat, sparks, open flames or other sources of ignition."

VII. Agency Conclusions

The data in support of this NADA comply with the requirements of Section 512 of the Act and Section 514 of the implementing regulations. The data demonstrate that Revolution (selamectin) topical for cats, when used under labeled conditions of use, is effective against hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise and proper diagnosis are required to determine the existence of heartworm infections and sarcoptic mange infestations and to monitor the safe use of the product.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for non-food producing animals qualifies for THREE years of marketing exclusivity beginning on the date of approval because the supplemental application contains substantial evidence of the effectiveness of the drug involved, or any studies of animal safety, required for the approval of the application and conducted or sponsored by the applicant. The three years of marketing exclusivity applies to only the indication for the control of hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections for which the supplemental application was approved.

Pfizer, Inc. Patent No. 5,981,500

VIII. Labeling (Attached)

- A. Package Insert
- B. Carton Label for cats (15 mg and 45 mg)

Page 3 of 4

NADA 141-152, Approved by FDA

REVOLUTION™ (Selamectin)
Topical Parasiticide For Dogs and Cats

CAUTION:

US Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:

Revolution (selamectin) Topical Parasiticide is available as a colorless to yellow, ready to use solution in single dose tubes for topical (dermal) treatment of dogs and cats six weeks of age and older. The content of each tube is formulated to provide a minimum of 2.7 mg/lb (6 mg/kg) of body weight of selamectin. The chemical composition of selamectin is (5Z,25S)-25-cyclohexyl-4'-O-de(2,6-dideoxy-3-O-methyl- α -L-arabino-hexopyranosyl)-5-demethoxy-25-de(1-methylpropyl)-22,23-dihydro-5-hydroxyiminoavermectin A_{1a}.

INDICATIONS:

Revolution kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations in dogs and cats. Revolution also is indicated for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*) in dogs, and the treatment and control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. Revolution is recommended for use in dogs and cats six weeks of age and older.

WARNINGS:

Not for human use. Keep out of the reach of children.

May be irritating to skin and eyes. Wash hands after use and wash off any product in contact with the skin immediately with soap and water. If contact with eyes occurs, then flush eyes copiously with water. In case of ingestion by a human, contact a physician immediately. The material safety data sheet (MSDS) provides more detailed occupational safety information. For a copy of the MSDS or to report adverse reactions attributable to exposure to this product, call 1-800-366-5288.

Flammable - Keep away from heat, sparks, open flames or other sources of ignition.

PRECAUTIONS:

Use with caution in sick, debilitated or underweight animals (see SAFETY).

Prior to administration of Revolution, dogs should be tested for existing heartworm infections. At the discretion of the veterinarian, infected dogs should be treated to remove adult heartworms. Revolution is not effective against adult *D. immitis* and, while the number of circulating microfilariae may decrease following treatment, Revolution is not effective for microfilariae clearance.

Hypersensitivity reactions have not been observed in dogs with patent heartworm infections administered three times the recommended dose of Revolution. Higher doses were not tested.

ADVERSE REACTIONS:

Following treatment with Revolution transient localized alopecia with or without inflammation at or near the site of application was observed in approximately 1% of 691 treated cats. Other signs observed rarely ($\leq 0.5\%$ of 1743 treated cats and dogs) included vomiting, loose stool or diarrhea with or without blood, anorexia, lethargy, salivation, tachypnea, and muscle tremors.

DOSAGE:

The recommended minimum dose is 2.7 mg selamectin per pound (6 mg/kg) of body weight.

Administer the entire contents of a single dose tube of Revolution topically in accordance with the following tables. (see ADMINISTRATION for the recommended treatment intervals).

Cats (lb)	Package color	mg per tube	Potency (mg/mL)	Administered volume (mL)
Up to 5	Mauve	15 mg	60	0.25
5.1-15	Blue	45 mg	60	0.75

For cats over 15 lbs use the appropriate combination of tubes.

Dogs (lb)	Package color	mg per tube	Potency (mg/mL)	Administered volume (mL)
Up to 5	Mauve	15 mg	60	0.25
5.1-10	Purple	30 mg	120	0.25
10.1-20	Brown	60 mg	120	0.5
20.1-40	Red	120 mg	120	1.0
40.1-85	Teal	240 mg	120	2.0

For dogs over 85 lbs use the appropriate combination of tubes.

Recommended for use in animals 6 weeks of age and older.

ADMINISTRATION:

Firmly depress the cap to puncture the seal on the Revolution tube; then remove the cap to administer the product.

Part the hair on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to empty its entire contents directly onto the skin in one spot. Do not massage the product into the skin. Due to alcohol content, do not apply to broken skin. Avoid contact between the product and fingers. Do not apply when the hair coat is wet. Bathing or shampooing the animal 2 or more hours after treatment will not reduce the effectiveness of Revolution. Stiff hair, clumping of hair, hair discoloration, or a slight powdery residue may be observed at the treatment site in some animals. These effects are temporary and do not affect the safety or effectiveness of the product. Discard empty tubes in your ordinary household refuse.

Flea Control in Dogs and Cats

For the prevention and control of flea infestations, Revolution should be administered at monthly intervals throughout the flea season, starting one month before fleas become active. In controlled laboratory studies >98% of fleas were killed within 36 hours. Results of clinical field studies using Revolution monthly demonstrated >90% control of flea infestations within 30 days of the first dose. Dogs and cats treated with Revolution, including those with pre-existing flea allergy dermatitis, showed improvement in clinical signs associated with fleas as a direct result of eliminating the fleas from the animals and their environment.

If the dog or cat is already infested with fleas when the first dose of Revolution is administered, adult fleas on the animal are killed and no viable fleas hatch from eggs after the first administration. However, an environmental infestation of fleas may persist for a short time after beginning treatment with Revolution because of the emergence of adult fleas from pupae.

Heartworm Prevention in Dogs and Cats

For the prevention of heartworm disease, Revolution must be administered on a monthly basis. Revolution may be administered year-round or at least within one month after the animal's first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. The final dose must be given within one month after the last exposure to mosquitoes. If a dose is missed and a monthly interval between dosing is exceeded then immediate administration of Revolution and resumption of monthly dosing will minimize the opportunity for the development of adult heartworms. When replacing another heartworm preventive product in a heartworm disease prevention program, the first dose of Revolution must be given within a month of the last dose of the former medication.

At the discretion of the veterinarian, cats ≥ 6 months of age may be tested to determine the presence of existing heartworm infections before beginning treatment with Revolution. Cats already infected with adult heartworms can safely be given Revolution monthly to prevent further infections.

Ear Mite Treatment in Dogs and Cats

For the treatment of ear mite (*O. cynotis*) infestations in dogs and cats, Revolution should be administered once as a single topical dose. A second monthly dose may be required in some dogs. Monthly use of Revolution will control any subsequent ear mite infestations. In the clinical field trials ears were not cleaned, and many animals still had debris in their ears after the second dose. Cleansing of the infested ears is recommended to remove the debris.

Sarcoptic Mange Treatment in Dogs

For the treatment of sarcoptic mange (*S. scabiei*) in dogs, Revolution should be administered once as a single topical dose. A second monthly dose may be required in some dogs. Monthly use of Revolution will control any subsequent sarcoptic mange mite infestations. Because of the difficulty in finding sarcoptic mange mites on skin scrapings, effectiveness assessments also were based on resolution of clinical signs. Resolution of the pruritus associated with the mite infestations was observed in approximately 50% of the dogs 30 days after the first treatment and in approximately 90% of the dogs 30 days after the second monthly treatment.

Nematode Treatment in Cats

For the treatment of intestinal hookworm (*A. tubaeforme*) and roundworm (*T. cati*) infections, Revolution should be applied once as a single topical dose. Monthly use of Revolution will control any subsequent hookworm or roundworm infections.

SAFETY:

Revolution has been tested safe in over 100 different pure and mixed breeds of healthy dogs and over 15 different pure and mixed breeds of healthy cats, including pregnant and lactating females, breeding males and females, puppies and kittens six weeks of age and older, and avermectin-sensitive collies. However, a kitten, estimated to be 5-6 weeks old (0.3 kg), died 8½ hours after receiving a single treatment of Revolution at the recommended dosage. The kitten displayed clinical signs which included muscle spasms, salivation and neurological signs. The kitten was a stray with an unknown history and was malnourished and underweight (see PRECAUTIONS).

DOGS: In safety studies Revolution was administered at 1, 3, 5, and 10 times the recommended dose to 6 week old puppies, and no adverse reactions were observed. The safety of Revolution administered orally also was tested in case of accidental oral ingestion. Oral administration of Revolution at the recommended topical dose in 5 to 8 month old beagles did not cause any adverse reactions. In a pre-clinical study selamectin was dosed orally to ivermectin-sensitive collies. Oral administration of 2.5, 10, and 15 mg/kg in this dose escalating study did not cause any adverse reactions; however, eight hours after receiving 5 mg/kg orally, one avermectin-sensitive collie became ataxic for several hours, but did not show any other adverse reactions after receiving

subsequent doses of 10 and 15 mg/kg orally. In a topical safety study conducted with avermectin-sensitive collies at 1, 3 and 5 times the recommended dose of Revolution, salivation was observed in all treatment groups, including the vehicle control. Revolution also was administered at 3 times the recommended dose to heartworm infected dogs, and no adverse effects were observed.

CATS: In safety studies, Revolution was applied at 1, 3, 5, and 10 times the recommended dose to six week old kittens. No adverse reactions were observed. The safety of Revolution administered orally also was tested in case of accidental oral ingestion. Oral administration of the recommended topical dose of Revolution to cats caused salivation and intermittent vomiting. Revolution also was applied at 4 times the recommended dose to patent heartworm infected cats, and no adverse reactions were observed.

In well-controlled clinical studies, Revolution was used safely in animals receiving other frequently used veterinary products such as vaccines, anthelmintics, antiparasitics, antibiotics, steroids, collars, shampoos and dips.

STORAGE CONDITIONS: Store below 30°C (86°F).

HOW SUPPLIED: Available in six separate dose strengths for dogs and cats of different weights (see Dosage). Each strength comes in a carton containing either 3 single dose tubes (puppy/kitten package) or 6 single dose tubes (all other sizes).

Distributed by:
Pfizer Animal Health
Exton, PA 19341, USA
Div. of Pfizer Inc, NY, NY 10017

www.revolutionpet.com

revolution™

Three single-dose tubes each containing 0.25 mL (15 mg) of selamectin for puppies & kittens ≤ 5 lbs in weight

Convenient once-a-month topical parasiticide for puppies & kittens ≤ 5 lbs in weight and at least 6 weeks of age



Three single-dose tubes

of selamectin



revolution™
(selamectin)



Caution: U.S. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
For use in animals only. Keep out of reach of children.
NADA 141-152, Approved by FDA

Three single-dose tubes each containing 0.25 mL (15 mg) of selamectin for puppies & kittens ≤ 5 lbs in weight and at least 6 weeks of age

revolution™
(selamectin)

FRONT

8511000

revolution™ (selamectin)

Parasiticide for Puppies & Kittens at least 6 weeks of age

Indications: Revolution kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations in puppies and kittens. Revolution also is indicated for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*) in puppies, and the treatment and control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in kittens. Revolution is recommended for use in puppies and kittens 6 weeks of age and older.

Warnings: Not for human use. Keep out of reach of children. May be irritating to skin and eyes. Wash hands after use and wash off any product in contact with the skin immediately with soap and water. If contact with eyes occurs, flush eyes copiously with water. In case of ingestion by a human, contact a physician immediately. The material safety data sheet (MSDS) provides more detailed occupational safety information. For a copy of the MSDS or to report adverse reactions attributed to exposure to this product, call 1-800-366-5288.

Flammable - Keep away from heat, sparks, open flame, and other sources of ignition.

Store below 30°C (86°F).



Distributed by:
Pfizer Animal Health
Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

BACK

LOT
EXP



10-9660-00-X1
997

revolution™ (selamectin)

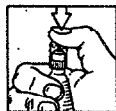
revolution™ (selamectin)

Dose and Administration: Revolution is recommended for use in puppies/kittens six weeks of age and older. Apply to the skin at the recommended minimum dose of 2.7 mg of selamectin per lb (6 mg/kg) of body weight once a month.

To facilitate application of Revolution, follow these basic steps. Revolution should be applied when the pet's haircoat is dry. However, bathing or immersing your pet in water 2 hours after application will not reduce the effectiveness of this treatment.



- 1 Remove the Revolution tube from its protective package.



- 2 Holding the tube upright, firmly depress the cap to puncture the applicator seal, then remove the cap.



- 3 Part the hair on the back of the animal at the base of the neck, in front of the shoulder blades, until the skin is visible.



- 4 Apply the tip of the Revolution tube directly to the skin without massaging. Squeeze the tube firmly to empty the contents in one spot. Avoid contact between Revolution and your fingers.

Discard empty tubes in your ordinary household refuse.

Q. Can I give my pet a bath after administration?

A. Yes, studies show that effectiveness is not reduced by bathing or immersing your pet in water two hours after application.

Q. How safe is Revolution for my pet?

A. Revolution has demonstrated a wide margin of safety in healthy animals 6 weeks of age and older. In field studies, vomiting, diarrhea and temporary, localized hair loss at the application site were observed in <1% of the treated animals.

Q. When can I play with my pet following treatment with Revolution?

A. You may hold or play with your pet any time after the area on which Revolution was applied is dry. You should avoid contact with application site when wet.

Q. Are there any precautions I should consider when using Revolution?

A. As with any prescription medication, you should always follow label directions. For topical use only. Use with caution in sick, debilitated or underweight animals.

Q. How should I store Revolution?

A. Revolution should be stored in its original carton at or below room temperature of 30°C or 86°F. After application, empty tubes can be placed in your normal household refuse for disposal.

See package insert for full product information.

5 27/32" x 3/4" x 5 7/8"
Die# L28588R12



PMS 110



PMS 688



Black

10-9660-00-X1 Facsimile Draft #1 7/8/99
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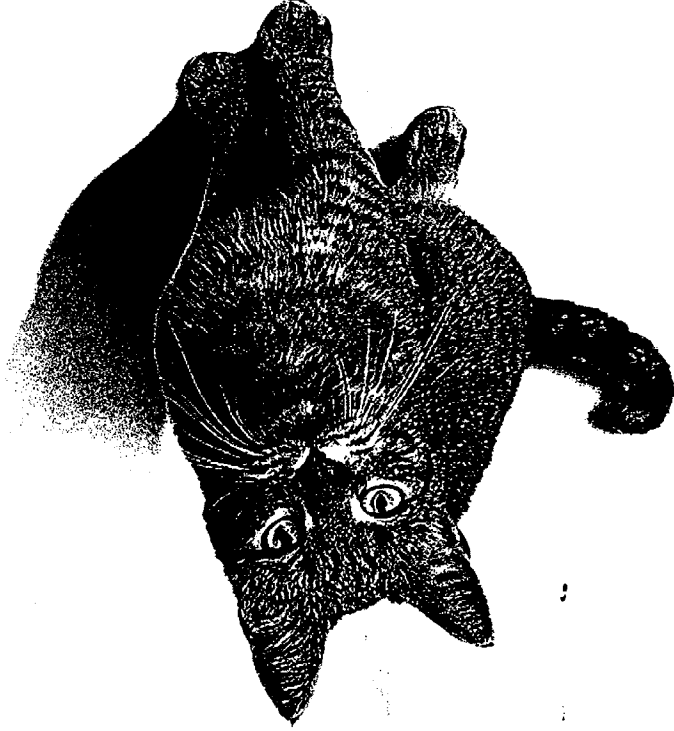
(Inside)

Front

revolution™
(selamectin)

Six single-dose tubes each containing 0.75 mL (45 mg)
of selamectin for cats 5.1-15 lbs in weight
and at least 6 weeks of age

revolution™
(selamectin)



Convenient once-a-month topical parasiticide for
cats 5.1-15 lbs in weight and at least 6 weeks of age



Caution: U.S. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
For use in animals only. Keep out of reach of children.
NADA 141-152, Approved by FDA



Six single-dose tubes each containing 0.75 mL (45 mg)
of selamectin for cats 5.1-15 lbs in weight
and at least 6 weeks of age

revolution™
(selamectin)

8512000

revolution™ (selamectin)

Parasiticide for Cats at least 6 weeks of age

Indications: Revolution kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations and intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. Revolution is recommended for use in cats 6 weeks of age and older.

Warnings: Not for human use. Keep out of reach of children. May be irritating to skin

and eyes. Wash hands after use and wash off any product in contact with the skin immediately with soap and water. If contact with eyes occurs, flush eyes copiously with water. In case of ingestion by a human, contact a physician immediately. The material safety data sheet (MSDS) provides more detailed occupational safety information. For a copy of the MSDS or to report adverse reactions attributed to exposure to this product, call 1-800-366-5288.

Flammable - Keep away from heat, sparks, open flame, and other sources of ignition.

Store below 30°C (86°F).

Distributed by:
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NY, NY 10017



LOT
EXP

revolution™
(selamectin)

Six single-dose tubes each containing 0.75 mL (45 mg) of selamectin for cats 5.1-15 lbs in weight and at least 6 weeks of age



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revolution™ (selamectin)

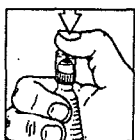
revolution™ (selamectin)

Dose and Administration: Revolution is recommended for use in cats six weeks of age and older. Apply to the skin at the recommended minimum dose of 2.7 mg of selamectin per lb (6 mg/kg) of body weight once a month.

To facilitate application of Revolution, follow these basic steps. Revolution should be applied when the pet's haircoat is dry. However, bathing or immersing your pet in water 2 hours after application will not reduce the effectiveness of this treatment.



- 1** Remove the Revolution tube from its protective package.



- 2** Holding the tube upright, firmly depress the cap to puncture the applicator seal, then remove the cap.



- 3** Part the hair on the back of the animal at the base of the neck, in front of the shoulder blades, until the skin is visible.



- 4** Apply the tip of the Revolution tube directly to the skin without massaging. Squeeze the tube firmly to empty the contents in one spot. Avoid contact between Revolution and your fingers.

Discard empty tubes in your ordinary household refuse.

Q. Can I give my pet a bath after administration?

- A. Yes, studies show that effectiveness is not reduced by bathing or immersing your pet in water two hours after application.

Q. How safe is Revolution for my pet?

- A. Revolution has demonstrated a wide margin of safety in healthy animals 6 weeks of age and older. In field studies, vomiting, diarrhea and temporary, localized hair loss at the application site were observed in <1% of the treated animals.

Q. When can I play with my pet following treatment with Revolution?

- A. You may hold or play with your pet any time after the area on which Revolution was applied is dry. You should avoid contact with application site when wet.

Q. Are there any precautions I should consider when using Revolution?

- A. As with any prescription medication, you should always follow label directions. For topical use only. Use with caution in sick, debilitated or underweight animals.

Q. How should I store Revolution?

- A. Revolution should be stored in its original carton at or below room temperature of 30°C or 86°F. After application, empty tubes can be placed in your normal household refuse for disposal.

See package insert for full product information.

Inside